DEC 22 2004

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE POLYPROPYLENE HERNIA MESH
Common Name:	Polypropylene Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery Devices
Establishment Registration Number:	2025240
Contact Person:	Michael Ivey Regulatory Affairs Medical Products Division W. L. Gore & Associates, Inc. 3450 West Kiltie Lane Flagstaff, AZ 86002-0500 Telephone: (928) 864-3790 Facsimile: (928) 779-3480 E-mail: *mivey@wlgore.com*

Performance Standards

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The GORE POLYPROPYLENE HERNIA MESH is used as reinforcement during surgical repairs of hernias and other soft tissue deficiencies.

GORE POLYPROPYLENE HERNIA MESH is comprised of non-absorbable, knitted 100% polypropylene monofilaments. The GORE POLYPROPYLENE HERNIA MESH is provided STERILE for single use only and offered in several sizes and shapes to accommodate the type and approach of the operation.

The GORE POLYPROPYLENE HERNIA MESH will be supplied in sheets ranging from a rectangular configuration that is 2.5 x 10 cm to a rectangular configuration that is 25 x 35.5 cm. Also available is a pre-shaped oval configuration that is 6.5 x 13 cm.

The GORE POLYPROPYLENE HERNIA MESH can be trimmed to the desired size and shape using sharp surgical scissors. The mesh should be sutured or tacked to host tissue avoiding excessive tension.

Indications for Use

The GORE POLYPROPYLENE Hernia Mesh is a sterile, non-absorbable, knitted polypropylene monofilament mesh intended for the reconstruction of hernias and soft tissue deficiencies. Examples of applications where the GORE POLYPROPYLENE HERNIA MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, incisional, epigastric, and intermuscular).

Muscle flap reinforcement

Substantially Equivalent Devices

In W. L. Gore & Associates, Inc.'s opinion, the GORE POLYPROPYLENE HERNIA MESH is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- **Bard® Mesh (Davol, Inc. Cranston, RI) – Pre-amendment Device**
- **Prolene™ Soft Polypropylene Mesh (Ethicon Inc, Somerville, NJ) - K001122**
- **Atrium Lite™ Mesh (Atrium Medical Corp, Hudson, New Hampshire) – K002093**

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE POLYPROPYLENE HERNIA MESH is equivalent to the predicate devices. All device integrity test results for the GORE POLYPROPYLENE HERNIA MESH met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the. GORE POLYPROPYLENE HERNIA MESH through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

Mr. Michael Ivey
Regulatory Affairs
Medical Products Division
W.L. Gore & Associates, Inc.
3450 West Kiltie Lane
P.O. Box 2400
Flagstaff, Arizona 86003

Re: K043081
Trade/Device Name: Gore Polypropylene Hernia Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: November 5, 2004
Received: November 8, 2004

Dear Mr. Ivey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K043081

Indications for Use

510(k) Number (if known): K043081

Device Name: GORE POLYPROPYLENE HERNIA MESH

Indications for Use:

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Muscle flap reinforcement

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043081